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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,617	01/14/2005	Tommy Urban Skantze	1103326-0785	5110
7470 7590 05/05/2009 WHITE & CASE LLP PATENT DEPARTMENT 1155 AVENUE OF THE AMERICAS NEW YORK, NY 10036				
EXAMINER				
TRAN, SUSAN T				
ART UNIT		PAPER NUMBER		
1615				
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05/05/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,617

Applicant(s)

SKANTZE ET AL.

Examiner

S. Tran

Art Unit

1615

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/35108)
- Paper No(s)/Mail Date 07/07/08; 11/12/08
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 07/07/08 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the aqueous medium" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The 102 rejections of record have been withdrawn in view of Applicant's Remarks filed 02/10/09.

Claim Rejections - 35 USC § 103

Claims 1-10 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipp et al. US 6,607,784, in view of Luddecke et al. US 5,895,659.

Kipp teaches a process for preparing submicron size particles of an organic compound. The process comprising: 1) dissolving the organic compound in the water miscible first solvent to form a solution; 2) mixing the solution with an aqueous second solvent to precipitate the organic compound to form a pre-suspension; and 3) adding energy to the pre-suspension to form particles having an average effective particle size of 400 nm (abstract; column 4, lines 57-65; column 6, lines 32-41; and column 8).

Organic compound includes pharmaceutically active compound (column 5, lines 60-67). Energy adding step includes sonicating the dispersion of amorphous particles for 15-30 minutes at temperature ranges from about -30°C to 30°C (column 7, lines 49-67; and examples). The aqueous second solvent further comprises one or more surfactants such as polyvinyl pyrrolidone and sodium dodecyl sulfate (column 6, lines 42 through column 7, lines 1-8; column 8, lines 51-67; and examples).

Kipp does not explicitly teach the claimed mean particle size of from 10-280 nm. However, it would have been obvious to one of ordinary skill in the art to, by routine experimentation optimize the process of Kipp to prepare nanoparticle having particle size from 10-280 nm, because Kipp teaches the desirability for preparing particles having average effective size less than 400 nm (column 4, lines 49-56).

Kipp further does not expressly teach the rate of mixing such as rapid mixing in less than 30 seconds (10, 11, 13 and 20). However, it would have been obvious to one

of ordinary skill in the art to, by routine experimentation modify the process of Kipp to obtain the claimed invention. This is because Kipp teaches that the process conditions such as rate of mixing of solution, rate of precipitation and the like can be selected/optimize (column 5, lines 49-55).

However, to be more specific, Luddecke is cited for the teaching that rapid mixing technique is known in the art (see column 1, lines 41-48; column 5, lines 41-50; and examples). Luddecke also teaches the use of a rapid mixing technique to obtain particle having mean particle size of 0.03 μm (column 7, lines 16-20). Thus, it would have been obvious to one of ordinary skill in the art to modify the process for preparing submicron size particle of Kipp using the rapid mixing rate in view of Luddecke to obtain particle having submicron size. This is because Luddecke teaches the use of a rapid mixing technique to form a fine suspension that is stable on storage (column 7, lines 1-40), and because Kipp teaches the desirability for preparing a suspension with fine particle size of less than 400 nm.

Claims 1-10 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindrud et al. WO 00/44468 A1, in view of Luddecke et al. US 5,895,659.

Lindrud teaches a process for preparing submicron size crystalline comprising: combining a solution of a pharmaceutical compound to be crystallized and an aqueous phase to form a precipitation (page 4, 2nd paragraph). Lindrud further teaches the use

of surfactant (page 4, 3rd paragraph). Sonicating the precipitate to obtain submicron size crystalline (pages 4-5). Example 1 discloses upon completion of crystallization, the product is filtered, washed and dried to obtain submicron particles (the claimed isolating step). Example 1 further discloses the temperature is maintained at 2°C throughout the crystallization.

Lindrud is silent as to the teaching of the rate of mixing. However, absent of evident to the contrary, the burden is shifted to applicant to show that the process of Lindrud does not provide rapid mixing. This is because Lindrud teaches a process for crystallizing submicron size particles that provides superior crystal structure when compared with particles formed by standard slow crystallization (page 2, lines 13-17). However, to be more specific, Luddecke is cited for the teaching that rapid mixing technique is known in the art (see column 1, lines 41-48; column 5, lines 41-50; and examples). Luddecke also teaches the use of a rapid mixing technique to obtain particle having mean particle size of 0.03 μm (column 7, lines 16-20).

Thus, it would have been obvious to one of ordinary skill in the art to modify the process for preparing submicron size particle of Lindrud using the rapid mixing rate in view of Luddecke to obtain particle having submicron size. This is because Luddecke teaches the use of a rapid mixing technique to form a fine suspension that is stable on storage (column 7, lines 1-40), and because Luddecke teaches that rapid mixing technique is well known in the art.

Response to Arguments

Applicant's arguments filed 02/10/09 have been fully considered but they are not persuasive.

Applicant argues that Kipp states at column 4, line 55, that a particle size of less than 400 am is preferable. However, as acknowledged by the Examiner, Kipp does not show how to obtain a particle size less than 400 nm. Furthermore, none of examples 1-4 of Kipp shows rapid mixing. Although Kipp states at column 7, lines 30-31 that the addition rate is dependent on the batch size and precipitation kinetics for the organic compound, Kipp does not suggest that rapid mixing provides a particle size of flora 30-280nm as claimed. Therefore, even if it were possible to modify the process of Kipp as alleged by the Examiner, it cannot be said in the absence of hindsight that Kipp, at the time the claimed invention was made, suggested rapid mixing to form an initial dispersion of amorphous particles to obtain nanocrystalline particles having a mean particle size of from 10 to 280nm. Kipp is silent that rapid mixing is an essential process step to the unexpected and advantageous formation of nanocrystalline particles having a mean particle size of from 30-280 nm as claimed.

However, in response to applicant's arguments, Kipp is cited in view of Luddecke for the teaching that rapid mixing is a well known technique in the art, and that using the rapid mixing step to obtain a fine particle suspension having mean particle size falls within the claimed range, namely, average particle size of 0.03 μm (column 7, lines 10-36).

Lindrud does not suggest the claimed process step of forming a dispersion of amorphous particles. Nor does Lindrud suggest the advantageous effect on reducing mean particle size by forming an initial suspension of amorphous prior to sonication. For all of the foregoing reasons, a *prima facie* case of obviousness has not been established. Withdrawal of the §103 rejection in view of Lindrud is requested.

However, in response to applicant's arguments, Lindrud is cited in view of Luddecke for the teaching that rapid mixing is a well known technique in the art, and that using the rapid mixing step to obtain a fine particle suspension having mean particle size falls within the claimed range, namely, average particle size of 0.03 µm (column 7, lines 10-36).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615

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